

NIST-NACLA MEMORANDUM OF UNDERSTANDING

Streamlining Laboratory Accreditation, Improving Commerce

FACT SHEET

Testing, certification and related activities assure that products and processes meet regulatory or procurement requirements or voluntary standards. If widely accepted, the results provide the equivalent of a passport-complication-free entry to domestic and foreign markets. In the global economy, with its increasing reliance on advanced technology and the growing international interest in health and safety matters, testing and other so-called conformity assessment requirements also are increasing.

An occasional--and unwanted--consequence of these trends is greater complexity, which, in turn, can lead to redundancy and inefficiency. The memorandum of understanding between the Commerce Department's National Institute of Standards and Technology and the National Cooperation for Laboratory Accreditation, a private-sector, volunteer organization, addresses one major source of this complexity: the somewhat confusing hierarchy of programs that evaluate the competence of laboratory accreditors. These accreditors evaluate the competence of testing and calibration laboratories and their compliance with specific technical requirements. Totalling about 100 in the United States, laboratory accreditors assess the proficiency of some 50,000 testing laboratories.

Many testing and calibration laboratories undergo multiple accreditation audits to satisfy various government and industrial requirements, even though scopes of accreditation often are similar or overlapping. Also, federal agencies differ greatly in their approaches to assessing whether products or services meet procurement or regulatory requirements. Trade agreements introduce yet another variable, stipulating procedures for designating testing laboratories to carry out activities intended to reduce technical obstacles to market entry.

Under the MOU, NIST and NACLA aim to create the organizational framework and operational mechanisms needed for a broadly recognized U.S. system for accrediting testing and calibration laboratories.

The goal is to simplify processes for demonstrating that products comply with domestic and foreign requirements. A summary of the agreement, signed on July 13, 2000, follows.

Basic Elements

Purpose of MOU: Achieve a coordinated U.S. system for the accreditation of testing and calibration laboratories, so as to eliminate unnecessary duplication and inefficiencies in both public- and private-sector use of laboratory accreditation.

Organizations: An agency in the Commerce Department's Technology Administration, **NIST** is charged with coordinating federal, state and local conformity assessment (including laboratory accreditation) activities with those of the private sector, as described in the National Technology Transfer and Advancement Act of 1995. Incorporated in 1998, **NACLA** is a private-sector, nonprofit, volunteer organization, devoted to creating an internationally accepted national infrastructure for recognizing competent accrediting bodies that adhere to internationally accepted performance standards. NACLA's approximately 100 member organizations believe that a test or calibration should be performed only once by an accredited laboratory and that the results should be accepted worldwide.

Term: The MOU will remain in effect for five years and may be renewed by mutual agreement.

Non-Exclusivity: The MOU does not preclude either NIST or NACLA from entering into other MOUS, agreements or arrangements related to laboratory accreditation.

NIST and NACLA Commitments

The MOU commits NIST:

- To encourage government agencies at all levels to accept the use of laboratory accreditation bodies recognized by NACLA.
- To work with other federal agencies to ensure that agency-unique accreditation requirements are understood by NACLA and incorporated into relevant NACLA evaluations.
- To treat NACLA recognition of laboratory accreditors as a suitable alternative to direct NIST recognition under its National Voluntary Conformity Assessment System Evaluation (NVCASE) program.
- To accept NACLA recognition of U.S. laboratory accreditors that accredit laboratories to the technical requirements of international mutual recognition agreements in which NIST is named a U.S. designating authority. (Examples are the electromagnetic compatibility sectoral annex of the U.S.-European Union N4RA and the Asia-Pacific Economic Cooperation NIRA for Conformity Assessment of Telecommunications Equipment.)
- To ensure that NACLA recognition of laboratory accreditation bodies is carried out in conformance with criteria specified in the MOU and that NACLA also fulfills the specific requirements of referenced international agreements.
- To encourage U.S. accreditors to seek NACLA recognition.
- To work with other government agencies to reduce duplicative audits and requirements and to monitor the progress of these efforts and the resulting savings.
- To inform NACLA of changes in government laboratory accreditation policies.

The MOU commits NACLA:

- To follow accepted international standards and guides and to accommodate relevant government requirements in the implementation of its recognition program.
- To properly evaluate the competence of laboratory accreditors so as to ensure that accredited laboratories meet the requirements of foreign governments participating in MRAs for which NIST is the designating authority.
- To submit to periodic third-party assessments so that NIST can verify that NACLA operations conform to the MOU's requirements and specifications.
- To maintain integrity and impartiality in the operation of its recognition program.
- To establish an impartial and objective appeals procedure.
- To encourage private- and public-sector entities to use NACLA-recognized accreditors.
- To encourage laboratory accreditation bodies to seek NACLA recognition.
- To work with private-sector bodies to reduce duplicative audits and requirements and to monitor the progress of these efforts and the resulting savings.

Anticipated Benefits

For Government Agencies:

- Improved confidence in the qualifications of laboratory accreditation bodies that agencies can rely on for regulatory, procurement and other purposes.
- Significant resource savings, since accreditor-recognition mechanisms enabled by the MOU can eliminate the need for agencies to operate their own laboratory accreditation/approval programs, without compromising their statutory responsibilities to protect public health and safety.
- Practical assistance to agencies with conformity-assessment obligations stemming from the increasing number of international trade agreements.

For U.S. industry:

- Improved assurance that testing and calibration laboratories are qualified to meet the requirements of manufacturers and their suppliers.
- Reduction in technical barriers to U.S. exports and in the need for re-testing, advancing industry's goal of "tested once, accepted everywhere."
- Elimination of the need for companies to operate their own laboratory approval programs.

For calibration and testing laboratories:

- Elimination of unnecessary duplicate accreditation requirements with a concomitant reduction in accreditation costs for many laboratories.

- A consistent accreditation standard with which to comply.
- Increased domestic and international recognition of U.S. laboratories' test and calibration data.

For a Laboratory Accreditation Body:

- A credible and highly visible means of demonstrating compliance with ISO/IEC Guide 58, the accepted international standard of competence.
- A basis for gaining acceptance by NIST, other relevant government agencies, and U.S. industrial firms for technical services provided in support of domestic needs and trade agreement requirements.
- Enhanced international recognition of accreditors and their laboratory customers.

For Additional Information about the NACLA-NIST MOU, contact:

Mark Bello at NIST, (301) 975-3776, mark.bello@nist.gov,

or Joe O'Neil at NACLA, (301) 975-8406.

July 2000